

Improving practice through clinical research

Using single-case experimental design to answer a clinical question

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KEYWORDS

CLINICAL RESEARCH COLLABORATIVE PRACTICE DEVELOPMEN-TAL LANGUAGE DISORDER

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It is becoming increasingly achievable for speech-language pathologists (SLPs) to conduct research in a clinical context to inform practice. This clinical insights paper describes and reflects upon the collaborative processes taken by a clinician to conduct research to answer a clinical intervention question, within an evidence-based framework (E³BP), using single-case experimental design (SCED). A recently completed project which used SCED to explore the treatment of grammar difficulties in early school-aged children with developmental language disorder is referred to as a case example. A time log of the project is also discussed. These data suggested that, although time spent adding research tasks to clinical tasks may seem time-consuming initially, it adds value to professional development. This is especially the case when there is the possibility to contribute to the current evidence base. Advancements in our understanding of E³BP, intervention study design, and collaborative approaches, support capacity and confidence of SLPs in conducting research to inform clinical practice.

peech-language pathologists (SLPs) are encouraged to work within an evidence-based practice framework (Speech Pathology Australia [SPA], 2020a). In line with this framework, an evidence-based approach to clinical decision-making values and acknowledges the importance and integration of three core components: (a) client context factors, (b) clinical context factors, and (c) research evidence (E3BP). Client context factors can be profiled within the World Health Organization's International Classification of Functioning, Disability and Health (WHO ICF) (World Health Organization, 2001), acknowledging diagnosis, strengths, weaknesses, impact of impairment, and family/school centred therapy goals. Clinical context factors include clinician knowledge, experience and expertise, as well as service provider policies. Research evidence refers to the best available scientific evidence to

support the selection of intervention approaches that align with client and clinician context factors.

However, drawing on evidence to inform a selected intervention is only part of the story; it is also an ethical and professional obligation to collect data to evaluate whether the approach works for/with the selected client (sometimes referred to as practice-based evidence). SLP professional bodies (e.g., American Speech and Hearing Association, Speech Pathology Australia, Royal College of Speech-Language Therapists) acknowledge the role of SLPs contributing to the evidence-base. This is clear in the *Professional Standards for Speech Pathologists in Australia* Standard 2.7: "Contribute to the speech pathology evidence base: 2.7c We participate in research that contributes to the evidence base of the profession" (SPA, 2020a, p. 14).

A recent narrative review of the literature reports on the growing trend of researchers looking to practice stakeholders (e.g., clinicians) to bridge the gap between research and practice, and to make research initiatives more relevant to clinical contexts (Greenhalgh et al., 2016). One example is the SPA-funded grants scheme supporting joint research projects between clinicians and researchers (SPA, 2020b). The aim of this particular grant is to fund a joint project (maximum of \$30,000) consisting of clinician(s) and researcher(s) embedded within a clinical context which will contribute to the evidence-base for communication and swallowing disorders. Projects may address research questions arising from clinical practice, or build the external validity of an existing research study by extending it to the clinical context. Despite growing support, there is evidence to suggest that clinicians find it difficult to engage in research, with barriers including time, ethics processes, approval from line managers, and knowledge of research design and statistical analysis, influencing activities and outcomes (Finch et al., 2013; Pickstone et al., 2008).

At the 2016 Speech Pathology Australia National Conference, Dr Susan Ebbels, in her keynote address, challenged clinicians to contribute to the evidence base and outlined a framework for conducting and evaluating clinical intervention research with particularly helpful guidelines focused on matching most appropriate research designs to clinical questions and contexts (Ebbels, 2017). Within the paper, Ebbels discussed the use of within-participant design with single baseline and control items and within-participant multiple baseline design as research designs particularly suited to clinical contexts. Both of these designs may be considered variations of single-case experimental designs (SCEDs).

Single-case experimental designs

SCEDs provide the opportunity for clinicians and researchers to evaluate intervention effectiveness. For within-participant designs, the participant (or client) serves as his/her own control (Byiers, 2019). Repeated measurements of a target behaviour are collected over a set number of sessions during baseline and intervention conditions (where the independent variable is manipulated), which are systematically introduced and withdrawn to demonstrate control and intervention effects. If there is no improvement during the baseline phase, but improvement on the target behaviour is observed during intervention phase, it is more likely change is due to intervention, rather than other factors, such as maturation or usual activities. An additional level of control can be achieved through measuring an untreated target behavior to increase confidence that the intervention has led to change. Ideally, the frequent assessment of repeated measures and manipulation of the independent variable (intervention) is replicated within and across a number of participants, and may also include a maintenance phase to evaluate retention of the target behaviour (Dallery & Raiff, 2014).

These are important characteristics which distinguish SCEDs from case studies, which are typically descriptive and use only pre- and post-intervention testing. Case study designs are considered lower levels of evidence and have a higher risk of clinicians misinterpreting results as treatment effects, rather than other factors such as maturation. While case studies are useful in exploring treatment acceptability and feasibility, the introduction of measures of control can elevate the design to a SCED.

SCEDs are particularly useful due to the flexibility in designs, and for allowing in-depth focus on individuals as the unit of measurement (Byiers, 2019). SCEDS are often used for research in special education and rehabilitation contexts, where there is difficulty recruiting large numbers of participants, or when great variability across participants is expected (Dallery & Raiff, 2014). Recent interest in the use of SCEDs as a relatively novel method to evaluate intervention effectiveness has highlighted the need to establish minimum standards for reporting. Both Kratochwill et al. (2013) and Tate et al. (2016) discuss the risks to accountability and bias in reporting unless a common understanding for the critical components of SCEDs is agreed upon. For example, within-participant designs require at least three replications over six phases, with a minimum of three testing points of repeated measures within each phase (Kratochwill et al., 2013). To demonstrate, this standard is met when three participants (i.e., replications) have repeated measurements probed three times in each of their baseline phases (i.e., one phase per participant) and their intervention phases (i.e., one phase per participant), totaling six phases. Further, Tate et al. (2016) have compiled guidelines (Single Case Reporting guidelines In BEhavioural interventions: SCRIBE) to facilitate clear and transparent reporting of SCEDs for appraisal and replication.

Advancements in quality standards increase confidence in the use of SCEDs for evaluating intervention effectiveness. In fact, the Oxford Centre for Evidence Based Medicine (OCEBM) currently considers randomised *n-of-1* trials (a variant of the SCED) as one of the highest levels of evidence (OCEBM, 2011). Thus, clinicians can consider SCEDs when looking to plan intervention blocks and robustly evaluate the effectiveness of their interventions. SCEDs are being used with increasing regularity in SLP

research. Examples include an efficacy study evaluating narrative intervention for pre-school children (Glisson et al., 2019), an evaluation of the effectiveness of PROMPT for the treatment of dysarthria in children with cerebral palsy (Ward et al., 2014), and the cycles approach to improve phonological knowledge (Rudolph & Wendt, 2014), as well as many examples in the field of aphasia (see Beeson & Robey, 2006; Howard et al., 2015) and AAC research (Laubscher et al., 2019).

Reflection on a case example

This clinical insights paper provides an outline and reflection upon the collaborative processes taken by a clinician to conduct research to answer a clinical intervention question, within an E3BP framework, using single-case experimental design (SCED). We will outline how a SCED was used in practice to answer a clinical question (Calder et al., 2018). This project was presented at the SPA 2017 National Conference, and the data have since been published. Here, we aim to report descriptively on planning and implementation processes and time spent on specific tasks during the project to assist clinicians with evaluating the benefit of using SCEDs clinically in consideration of the practical constraints to practice. In the section to follow, we will address: (a) client context factors: (b) clinical context factors; and (c) research evidence to formulate a clinical question.

The project

Based on information organised according to the E³BP framework, the following clinical question was formulated:

Does past tense marking improve significantly in children aged 6 to 7 years with developmental language disorder (DLD) following combined explicit and implicit intervention?

As with any clinical question, to answer it confidently, it is necessary to regularly collect data to monitor progress and evaluate outcomes. However, given the lack of evidence to support this specific question, we implemented a SCED using robust methodology to address the clinical question and contribute to the evidence.

Three children aged 6 to 7 years with DLD were recruited from a specialised educational program. Using an across-participant multiple baseline (SCED), the children were seen one-on-one, twice a week for five weeks in 45 minute sessions, resulting in seven and a half hours of intervention. The focus of the intervention for all three children was to improve production of regular past tense (–ed).

Client context factors included profound receptive and expressive grammar difficulties. In particular, regular past tense marking is considered a reliable clinical marker to identify children with DLD (Redmond et al., 2019). Clinical context factors included an understanding that children with DLD present with grammar difficulties despite experiencing adequate opportunities learn from their ambient linguistic environment (Leonard, 2014). Service provider policies included the requirement to provide evidence-based practice to improve client outcomes based on individual needs. Research evidence for grammar interventions is equivocal for children aged 6 to 7 years.

Ebbels (2014) has indicated that, broadly, implicit interventions (which enhance naturalistic interactions between children and adults) are effective to a degree for children under the age of 5. Alternatively, explicit interventions (which overtly teach children the rules of grammar) are effective for children over the age of 8.

This suggests a gap in the literature identifying effective interventions for 6–7-year-old children. Further, if children with DLD tend to have difficulty learning from their ambient linguistic environment, would simply enhancing the input through implicit interventions be sufficient enough to be effective? Perhaps younger children would also benefit from being explicitly taught the rules of grammar as well as using implicit strategies. One such explicit approach is the Shape Coding™ system (Ebbels, 2007), which is used to systematically represent syntax and morphology using visual cues, including shapes and arrows.

The process

The process of implementing the project will be discussed in terms of using a SCED framework to answer a clinical question. The project was carried out by a clinician in collaboration with researchers. The process is summarised in Table 1, which notes elements within the Single Case Reporting Guideline in BEhavioural interventions (Tate et al., 2016).

Table 1. The collaborative process of implementing SCED to answer a clinical question using SCRIBE (Tate et al., 2016).

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SCRIBE topic	Activity/description	SCRIBE item number
Design	Multiple baseline across participant design was selected, including 5-week baseline phase, 5-week intervention phase, and a 5-week maintenance phase.	5
Measures	Repeated measures including a target behaviour (regular past tense) and a control behaviour (possessive 's) were selected.	14
Ethics	The clinician obtained ethics approval from the Department of Education (employer) and the researchers obtained ethics approval from the University Human Research Ethics Committee.	13
Intervention	Explicit grammar intervention combining the Shape CodingTM system with a systematic cueing hierarchy. Children were seen 1:1, 2 x per week for 5 weeks in 45-minute sessions, resulting in 7.5 hours of intervention.	16
Participants	3 x 6–7-year-old children with DLD were recruited.	11
Setting	Children's school, to minimise disruption to classroom participation, and facilitate contact with classroom teachers.	12
Analyses	Relevant statistical analyses for SCEDs were selected.	18
Outcomes and estimations	The primary outcome was past tense production. The first client made gains in during intervention phase. The second client made gains during the maintenance phase. The third client did not demonstrate measurable gains.	20

Planning and Implementation

In order to manipulate the introduction of intervention as an independent variable with control, the implementation of a baseline phase is critical. To further contribute to robustness of a SCED, a control behaviour can be probed throughout baseline and intervention phases. In collaboration with researchers who possessed knowledge and resources (e.g., access to textbooks, journal articles) regarding research design, a multiple-baseline (target behaviour and control behaviour) replicated across participant (three clients) design was selected.

The target behaviour probed through repeated measurement was regular past tense production, a known area of deficit for the clients, as well as for children with DLD in general. The clients presented with multiple errors in inflectional morphology, so possessive 's was selected as a control measure, as the team agreed it would be unlikely possessive 's as a type of nominal inflection would improve with intervention targeting verbal inflection (i.e., regular past tense). The repeated measures were adapted from the Grammar Elicitation Test (Smith-Lock et al., 2013), which is a criterion-referenced test designed to elicit the production of multiple morphosyntactic structures, including regular past tense and possessive 's. Subsequently, a five-week baseline phase was planned, in which repeated measures would be collected at three testing points. This was followed by a five-week intervention phase, in which repeated measures would be collected at 10 testing points. If there was improvement in the intervention phase, and not in the baseline phase, this would increase confidence that the change is attributable to intervention. To assess maintenance, we also planned a five-week maintenance phase, where repeated measures would be re-administered at two testing points.

Since the research question was novel, there was the potential that findings could make a publishable contribution to the evidence base. Therefore, the team sought ethical approval through their respective channels. That is, the researchers sought approval through a university human research ethics committee, and the clinician sought ethical approval through the Department of Education Western Australia as his employer. The clinician drew upon the experience and expertise of the researchers to complete relevant application forms, as well as design information sheets and recruitment letters for the parents of clients. This provided a key learning opportunity about the level of detail that is required in planning for the implementation of an intervention study—for example, consideration of the risks associated with withdrawing clients for individual therapy when they may otherwise be in the classroom. Therefore, it was pertinent to draw up a comprehensive intervention plan to ensure the clinician was accountable if clients agreed to be recruited.

Intervention planning included contacting other researchers who had implemented similar interventions with different age ranges (i.e., Ebbels, 2007; Smith-Lock et al., 2015). The intervention procedures were planned as an explicit intervention which combined the Shape Coding™ system as an overlay to the systematic cueing hierarchy used in Smith-Lock et al. (2015). In Shape Coding™, paper shapes and arrows are used to explicitly teach children about the grammatical functions of morphosyntax using visual support and tactile manipulation. This was used in conjunction with scaffolded verbal feedback in response to student errors. Full details can be found in the appendices of Calder et al. (2018, pp. 186–189).

Once ethics approval was obtained, the clients' families consented to participate, and the intervention procedures were clearly documented, the baseline phase was implemented, followed by the intervention phase, and finally, the maintenance phase. To minimise disruption to the clients, the intervention was planned to be carried out at the school which they attended. This also allowed for regular contact with the clients' classroom teachers to provide feedback and "put a face" to the research. The clinician met with the researchers once the baseline phase was underway to ensure that the target and control behaviours were suitable to measure intervention effectiveness-that is, to confirm the clients presented with difficulties in production of the morphemes targeted in the intervention. Further, once the five-week intervention phase commenced, regular meetings between the clinician and researchers took place to discuss the implementation of intervention procedures, including any barriers, such as length of session or client engagement. Fortunately, such barriers were minimal to non-existent.

During the maintenance phase, data were collected by student speech pathologists blinded to the study as an opportunity to contribute to their professional competencies and add another level of control, and hence to the robustness of the study design. Once all data were collected, the clinician and researchers met to analyse the data. From the clinician's standpoint, this was the most challenging aspect of the project. However, the researchers' access to university statistical experts, resources, and software facilitated a valuable learning experience.

Following the implementation of a SCED to answer a clinical question, the clinician was able to arrive at the following conclusions regarding intervention effectiveness. The first client made gains on repeated measures of past tense, but not possessive 's. He was an ideal client, and his mother reported he even started to correct his younger sister's grammar after the intervention. The second client made gains on repeated measures of past tense, but not possessive 's; however, she was still clinically impaired. Interestingly, there was no significant improvement during the intervention phase, suggesting that she showed the most significant improvement after the completion of the intervention, during the maintenance phase. In her final assessment, she was very intentional in the way she produced regular past tense on probes, suggesting an increased meta-awareness of the structure. The third client did not improve on measures of past tense production. However, this client seemed to be the most responsive to intervention from a clinical perspective, in that he was showing positive responsiveness to therapy within sessions. Nonetheless, this success was not retained across sessions. Upon reflection, this client may have benefitted from some more role-reversal activities, where the client must respond to the clinician's errors to increase salience of grammatical errors in communication and his awareness of the goal of intervention.

The findings from the project allowed for the systematic evaluation of clinical effectiveness, as well as reflection on the elements of intervention that may or may not have suited certain clients.

Time commitment

The following section provides a time log of tasks that were carried out during the project. The time log has been parsed according to clinical tasks (those that would ordinarily be carried out during clinical practice) and research tasks (those carried out in addition to clinical

Table 2. Time spent on clinical tasks					
Task	Time (workplace) (hours)	Time (private) (hours)	Time (other)* (hours)		
Pre-assessment**	4.5	2	/		
Intervention	20	/	/		
Post- assessment**	3	/	6.75		
Total	25	2	6.75		
Aggregated total	36.25				

^{*} included blinded assessors that collected data during clinical time

work). Further, time has been separated into tasks completed within paid working hours, and those completed in private hours. This project was carried out over 17 working weeks. See Table 2 for a summary of time allocated for clinical tasks and Table 3 for a summary of time allocated to research tasks.

Clinical tasks

Clinical tasks included pre-assessment, intervention (which included intervention provision and progress notes), and post-assessment tasks. In total, 34.25 hours were spent on clinical tasks in working hours, and just two hours outside of work. These two hours are likely due to spending more time organising and collecting post-intervention data as a result of using SCED in clinical practice. Unsurprisingly, the task that took the majority of time was intervention; however, this only accounted for around half of the time (55.2%) and is probably not reflective of typical clinical work. That is, in typical practice, the majority of time would be spent providing intervention. As noted, the pre- and post-assessment tasks were likely to have taken more time than in typical clinical practice, as a broader battery of measures was used to increase confidence in findings. This is a common discrepancy between clinical and research

Table 3. Time spent on research tasks				
Task	Time (workplace) (hours)	Time (private) (hours)		
Meetings and follow up	9.33	1.5		
Ethics	0.5	3		
Repeated measures planning	3.5	3		
Intervention planning*	/	10.75		
Assessment checking and data collation	/	6		
Statistical analysis and interpretation	/	9		
Total	14.33	33.25		
Aggregated total	47.6			
Aggregated total * such as refining treatment p		cability		

^{**} included battery of assessments not likely to be used typically in clinical practice

practice. Additionally, blinded assessors were used post assessment, but would reflect time that would have otherwise been used in working hours.

Research tasks

Research tasks included meetings with researchers plus follow-up time, completing ethics applications, planning for repeated measures, planning for intervention, checking and collating assessment data, and statistical analysis and interpretation. Notably, intervention planning is a task that would typically be carried out clinically. However, intervention procedures were developed and refined with particular care to facilitate reflection on intervention responsiveness and to ensure replicability to increase the likelihood findings could be published, and that the intervention could be used into the future. In total, 14.33 hours (~ two working days) were spent on research tasks within working hours. It should be noted that support was provided by the clinician's line manager to allocate some working hours to this research project. However, 14.33 hours spread over 17 working weeks is more or less negligible, and most of that time was spent meeting with researchers for support (9.33 hours). The majority of research activity was spent in private time (69.6%), with intervention planning (10.75 hours) being the most time heavy task, shortly followed by time spent conducting statistical analyses and interpreting the results (9 hours). Given that these are two essential procedural aspects to conducting research, these time allocations should be unsurprising.

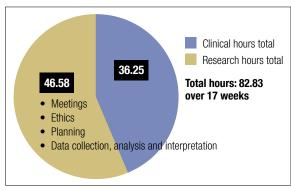


Figure 1. Time spent on clinical vs research tasks

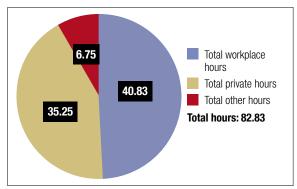


Figure 2. Time spent at work vs private

How much time was spent on the project?

A breakdown of time spent on clinical vs research tasks is presented in Figure 1, and work vs private time is presented in Figure 2. Out of the total 17 weeks, the project spanned, 83.85 hours were dedicated to the project. If clinical time is discounted, 47.6 hours (56.8%) additional time was spent on research specific tasks, with 33.25 hours (39.7%) spent

out of the clinicians' private time to complete the project. Adding the critical elements to clinical practice to conduct intervention research resulted in time commitments more than doubling, with the majority coming from hours outside of paid working time. This may seem like a great cost in order to use clinical research to improve practice. However, it is argued that this project increased confidence in the ability to evaluate the effectiveness of this particular intervention far beyond what is possible to do within "standard" clinical practice. That is, not only was effectiveness quantifiable, the findings ultimately made a contribution to the evidence base for the efficacy of grammar interventions for this age group of children with DLD.

A great deal of the time was spent either: meeting with researchers for support, which is in and of itself a form of professional development; or intervention planning. This became a clinical resource to use with future clients and to share with colleagues. Finally, the statistical procedures would likely have taken more time as a novel experience, and will conceivably take less time with increased practice. In summary, the results of this project, although time-consuming, were ultimately publishable and have made a contribution to the evidence base. Therefore, what might seem an initially expensive outlay was truly an investment to the clinician's own clinical practice and possibly even to the profession at large.

Take home messages

This journey has demonstrated that it is achievable for clinicians to conduct research in their workplaces. Further, researchers are often open and encouraging to lend their support to clinicians, whether it is a question about certain intervention techniques, study design, outcome measures or statistical analysis. Olswang and Goldstein (2017) outlined the roles of SLPs in research collaborations, placing great emphasis on the expertise SLPs bring to partnerships regarding service delivery needs and constraints. Integrating research into clinical practice is clearly a time-consuming task, adding to time spent working outside of working hours. However, if time spent adding research tasks to clinical practice is considered within the context of value adding to professional development and to the evidence base, an initial outlay of doubling time resources may be seen as a sound investment. This project demonstrates the benefit of using a SCED to evaluate effectiveness of intervention in a clinical context. Through advancements in the area of E3BP and intervention study design, and through openness to collaborate, SLPs are becoming increasingly capable of conducting research to inform clinical practice.

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